

TRICUSPID VALVE REGURGITATION IN PATIENTS UNDERGOING ENDOCARDIAL LEADS PLACEMENT

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ABSTRACT

Objective: To assess prospectively the presence and degree of tricuspid regurgitation (TR) after right ventricular (RV) lead placement utilizing 2-dimensional and doppler echocardiography in a group of patients implanted with Permanent pace-maker or implantable cardioverter defibrillator (ICD).

Study Design: Descriptive cross sectional study.

Place and Duration of Study: Study was conducted at OPD of AFIC/NIHD Rawalpindi from Jan to Jun 2019.

Methodology: One hundred patients after cardiac stimulation system implantation were included in this study. Patients with severe valve disease, heart failure, congenital heart disease, pre-existing pulmonary hypertension and presence of moderate or severe tricuspid regurgitation were excluded. M-mode, 2-dimensional and doppler echocardiographic studies were performed. Continuous-wave doppler measurements were made from apical four-chamber view in order to obtain maximum tricuspid flow velocities. A complete echocardiographic study was performed following device implantation. Echocardiographic measurements were repeated at 6-months of follow-up period. Those patients who developed tricuspid regurgitation were further assessed by color doppler, taking into account density and contour of the jet on continuous-wave doppler. Tricuspid regurgitation severity was classified into three groups: mild, moderate and severe according to the recommendations for non-invasive evaluation of native valvular regurgitation by the American Society of Echocardiography. The collected data was analysed by using SPSS-23.

Results: Out of 100 patients, 67 (67%) were males and 33(33%) were females with the mean age of 65.29 ± 12.02 years. All the patients had normal chambers dimensions before the procedure. 65 (65%) had leads screwed to RV apex while 35 (35%) had through RV septum. 83 (83%) patients received a dual chamber device, while 17 (17%) patients got single chamber (ventricular) device implanted. Following device implantation after 6 months mild TR was noted in 4 (4%), moderate TR in 4 (4%) and severe TR 2 (2%) in cases.

Conclusion: Tricuspid incompetence following endocardial leads implantation is not rare and occurred in approximately 10% of our patients. This complication may be preventable, because it is likely due to the interference of the endocardial lead with the TV.

Keywords: Permanent pacemaker, Tricuspid regurgitation, Implantable cardioverter defibrillators.

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INTRODUCTION

Implantation of devices like permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs) has exponentially increased in the 20th century due to increased life expectancy and wide range of available devices. Tricuspid regurgitation (TR) is a recognized complication of right ventricular (RV) endocardial lead placement. Post implantation tricuspid regurgitation is being recognized as an emerging problem, but its

incidence and clinical significance has not been well-established¹. Some of the studies have mentioned incidence, ranging from 7% to 39%^{2,3}.

Both 2-dimensional (2D) echocardiography and color doppler flow mapping are essential in diagnosing TR⁶. Advantages to echocardiography in the assessment of TR include that it is non-invasive, does not involve ionizing radiation, is ubiquitous in clinical settings and when performed comprehensively, can result in accurate determinations of TR severity and mechanism, as well as potential impacts of TR on RV size, func-

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tion and cardiac output^{16,17}. The severity is based on the direction and the size of the regurgitant jet, the presence of proximal flow convergence and vena contracta width⁶. The sensitivity and specificity of classifying TR as severe using vena contracta width ≥ 6.5 mm is 88.5% and 93.3%, respectively¹⁵.

Tricuspid regurgitation after lead placement can occur via multiple mechanisms. Functional or anatomical interference between lead and tricuspid apparatus as well as perforation or laceration of valves have all been accused as the causative mechanism^{4,5}. Other causes include scar formation or thrombus on the leads impairing closure. Another mechanism is asynchrony, resulting from abnormal right ventricle (RV) activation from a pacemaker⁷. Pseudo-TR can occur as a result of contraction of the atrium against a closed tricuspid valve, which can be corrected by restoring atrioventricular synchrony or patient having intrinsic rhythm⁸.

This study will help to assess the presence and degree of TR after right ventricular (RV) lead placement utilizing 2-dimensional and doppler echocardiography in patients undergoing implantation of Permanent pacemaker or Implantable Cardioverter defibrillator (ICD).

Tricuspid regurgitation is the backflow of blood from the right ventricle into the right atrium during systole⁹.

METHODOLOGY

This descriptive cross-sectional study was conducted at AFIC/NIHD Rawalpindi, from January 2019 to June 2019 after permission was sought from hospital ethics committee. Informed consent was taken from all patients recruited in this study. A total of 100 patients fulfilling the inclusion criteria were enrolled in study through non-probability purposive sampling. Inclusion criteria consisted of both genders of age between 25-90 years and LV ejection fraction $>50\%$ while exclusion criteria consisted of previous myocardial infarction, severe valve disease (severe stenosis and/or regurgitation of all heart valves), heart failure (ejection fraction $<50\%$), congenital heart

disease, pre-existing pulmonary hypertension and presence of moderate or severe tricuspid regurgitation.

M-mode, 2-dimensional and doppler echocardiographic studies were performed using a commercially available real-time scanner equipped with a 2.5-MHz transducer; all examinations and measurements were made according to the recommendations for non-invasive evaluation of native valvular regurgitation by the American Society of Echocardiography before implantation⁸. Continuous-wave doppler measurements were made from apical four-chamber view in order to obtain maximum tricuspid flow velocities. A complete echocardiographic study was performed following device implantation. Following data were collected: Age, Gender, Ejection fraction, Right ventricular basal diameter, TAPSE.

Echocardiographic measurements were repeated at 6-months of follow-up period. Those patients who developed Tricuspid Regurgitation (TR) were further assessed on the basis of jet area by color doppler, taking into account density and contour of the jet on continuous-wave doppler. TR severity was classified into three groups: mild, moderate and severe according to the recommendations for non-invasive evaluation of native valvular regurgitation by the American Society of Echocardiography. Measurements taken by one cardiologist was confirmed by another experienced one.

The collected data was analyzed in SPSS version 23. The severity and frequency of TR in the patients presenting in our hospital for either permanent pacemaker or ICD implantation, after lead insertion were measured. A p -values <0.05 were considered significant. Mean \pm SD was calculated for continuous variables while chi-square test was used to determine association.

RESULTS

Total 100 patients were included in the study after satisfying the inclusion criteria of the study. The clinical characteristics of the patients are summarized in table-I, 67 (67%) were males and 33 (33%) were females. Mean age (years) was $65.29 \pm$

12.02 with range of 64 from 27 to 91. All the patients had normal chambers dimensions before the procedure.

The ventricular leads were screwed to either RV apex or RV septum using active fixation leads. Sixty five (65%) had leads screwed to RV apex while 35 (35%) had through RV septum. Eighty three (83%) patients received a dual chamber device, while 17 (17%) patients got single chamber (ventricular) device implanted.

Table-I: Demographics and clinical characteristics.

Variables	Mean \pm SD / Frequency (%)
Age	65.29 \pm 12.02 years
Gender	
Male	67 (67%)
Female	33 (33%)
Site	
RV Apex	65 (65%)
RV Septal	35 (35%)
Type of Device	
PPM	79 (79%)
ICD	21 (21%)
TR	
Present	10 (10%)
Absent	90 (90%)
Severity of TR	
Mild	4 (4%)
Moderate	4 (4%)
Severe	2 (2%)
Chamber Placed	
Single	17 (17%)
Dual	83 (83%)
RV Basal Diameter	1.04 \pm 0.19
TAPSE	1.030 \pm 0.171

Following device implantation after 6 months mild TR was noted in 4 (4%), moderate TR in 4 (4%) and severe TR 2 (2%) in cases. There was no worsening of the severity of TR in patients with mild regurgitation following device implantation. The Mean \pm SD of RV basal diameter was 1.04 \pm 0.19 while TAPSE was 1.030 \pm 0.171. Chi-square test was applied to determine the association. Significant association of 0.01 was seen between device implantation and development of TR. The results of association are represented in table-II.

There was no statistical significance determined between the devices group PPM vs ICD and Severity of TR.

Table-II: Association between device implantation and TR.

Parameters	n (%)	p-value
Type of Device		
PPM	79 (79%)	0.01
ICD	21 (21%)	
Severity of TR		
Mild	4 (4%)	0.01
Moderate	4 (4%)	
Severe	2 (2%)	

DISCUSSION

This study revealed that TR after endocardial leads placement is a common occurrence than thought of. The prevalence of TR in normal hearts varies from 0-53% considering different echocardiographic techniques and varying definitions of TR^{10,11}. Our study also showed the results within this range i.e 10%. Previous studies have shown an incidence of worsening TR following placements of the leads from 7-39%³. This variation can be explained due to a number of reasons. First, the different ways in which the studies were conducted; most were retrospective, with sample sizes ranging from 23-410 patients. Secondly majority of studies used two-dimensional echocardiograms to evaluate TR but one study utilized three dimensional echocardiography and showed a higher occurrence of post device TR of 39%. Finally different studies used different time frame for assessment of TR^{1,2}.

Although the study by Kim *et al*¹⁸ found a higher frequency of TR in patients with ICD compared with PPM (32.4% vs 20.7%, $p=0.048$), However a significant association was seen in device implant and TR (p -value 0.05) but no independent significant association was revealed in our results. Moreover position of the lead in RV also had no effect on TR frequency. This is in accordance to a detailed echocardiographic study done by Krupa *et al*¹² on 86 patients with permanent pacemaker and ICD leads and they revealed that here is no difference in the incidence of TR, whether the lead passed through the central,

anterior, or posterior portion of the valve, or whether the right ventricular lead was placed at the apex, outflow tract.

In those patients in whom there was a mild TR present at baseline there was no worsening to moderate or severe TR at follow up after 6 months. The time course for TR development and progression after endocardial lead placement in the right ventricle is not fully defined. Although some studies have not detected an increase in TR acutely as assessed by 2D echocardiography after RV lead implantation, others have^{13,19}. Leibowitz *et al*¹³ described 35 patients with doppler echocardiograms obtained before and soon after permanent pacemaker implantation and found no acute worsening of tricuspid regurgitation following permanent pacemaker implantation. Studies to understand pathological basis of the valve regurgitation have demonstrated inflammatory changes occurring within the heart only days after implantation of the leads. When this inflammation progresses over weeks to months then it results in fibrotic tissue formation, which encapsulates the pacemaker lead and may result in fusion and adherence of the endocardial lead to the TV leaflets, chordae, and papillary muscles, culminating in TR. This has implications for the importance of early intervention if lead repositioning is contemplated, because repositioning the endocardial lead can be readily achieved shortly after lead implantation but can be difficult or impossible during the chronic stage²⁰.

There is a debate on the predictors of developing TR after cardiac device implantation⁷. Various investigations done on adults have found out that advanced age is a risk factor for developing TR (age range, 72–75 years)² whereas the pediatric study done by Webster *et al*¹⁴ (age range, 2–52 years) did not find age to be a factor.

LIMITATION OF STUDY

There were few important limitations which need to be highlighted. First, this was a single center experience in a relatively small group of patients, and the degree of TR seems dependent on the experience of the operator and institution.

Secondly, male were more in number so it is difficult to generalize our conclusion to women group. Finally this study was conducted using 2D echocardiography there is a possibility of under estimation of the severity of the TR. Advanced imaging modalities like 3D echocardiography or cardiac MRI have the ability to give a more objective and quantitative evaluation of anatomy and function of tricuspid valve. Due to its capability of obtaining an en face view of the valve, which helps in visualizing simultaneously movement of the three leaflets during the cardiac cycle, and their attachments to the tricuspid annulus.

CONCLUSION

Tricuspid incompetence following endocardial leads implantation is not rare and occurred in approximately 10% of our patients. This complication may be preventable, because it is likely due to the interference of the endocardial lead with the TV. It is important to have a high index of suspicion and to adopt a goal-oriented approach in using echocardiography to assess TV morphology and function in these patients. Future studies with early follow ups and advanced imaging in the form of 3D echocardiography can help in diagnosing and managing this complication at early stage.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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